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REMARKS

Reconsideration of the above referenced application is respectfully requested. Upon entry of the foregoing amendment, Claims 1-20 are presently pending. New Claims 19 and 20 have been added. Claims 1, 2, 4, 5, 6, 8, 9, 10, 12 and 18 have been amended. Claim 11 has been cancelled. Applicants reserve the right to pursue the subject matter of the cancelled claim in one or more continuation or divisional applications. No new matter has been introduced and entry of the amendment is requested.

Sequence Disclosure

The Office Action states that the application contains disclosures that fail to comply with the requirements of 37 CFR 1.821 through 1.825 based on the sequences provided on page 6 of the specification. The specification has been amended as set forth above such that it is in compliance with 37 CFR 1.821 through 1.825.

Claim Rejections

Page 2 of the Office Action states that Claim 18 is rejected under 35 U.S.C. 101 as allegedly directed to non-statutory subject matter. Claim 18 has been amended to clarify that the subject matter is an "isolated" host cell.

Rejections under 35 U.S.C. § 102(a)

Claim 1, 10, 14, 15 and 17-18 are rejected under 35 U.S.C. 102(a) as being anticipated by Chia et al.

Chia et al. is cited as disclosing a replication competent adenovirus vector comprising the EBV oriP-FR region and basal CMV IE promoter for expression of a reporter gene, luciferase or beta gal.

For anticipation under 35 U.S.C. § 102(a), a reference "must teach every aspect of the claimed invention either explicitly or impliedly. Any feature not directly taught must be inherently present." (MPEP §706.02). "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art

reference." Verdegaal Bros. v. Union Oil Co. of California, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987).

Chia does not teach or suggest a replication-competent adenovirus vector comprising an adenovirus gene essential for replication (i.e. E1A or E1B) under transcriptional control of an Epstein Barr Virus (EBV)-specific transcriptional regulatory sequence selected from the group consisting of a sequence upstream of the translational start codon for the LMP1 gene, presented as SEQ ID NO:1, a sequence upstream of the translational start codon for the LMP2A gene, presented as SEQ ID NO:2 and the Cp promoter sequence, presented as SEQ ID NO:3, as presently claimed.

Thus Chia et al. lacks both explicit description or a suggestion of the structural features of the invention as claimed which is required for anticipation under 35 U.S.C. § 102(b). Accordingly, the rejection should be withdrawn.

Rejections under 35 U.S.C. § 112, first paragraph, written description

Claims 1 and 8-18 are rejected under 35 U.S.C. 112, first paragraph as failing to comply with the written description requirement.

On page 4, the Office Action states that Applicants claim a replication competent adenoviral vector comprising a gene essential for replication under transcriptional control of an EBV specific TRE and that Applicants provide a written description for EBV TREs which are EBV specific transcriptional response elements. On page 5, the Office Action further states that Applicants disclose no non-EBV-TREs which preferentially direct expression in EBV-associated cancer cells and alleges that as such the skilled artisan would be unable to envision the non-EBV members of the claimed genus.

The guidelines for determining compliance with 35 U.S.C. 112 note that the written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant identifying characteristics, *i.e.*, structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus.

Description of a representative number of species does not require the description to be of such specificity that it would provide individual support for each species that the genus embraces. Applicants note that recitation in a claim of a generic element, for example a transcriptional response element, does not require that the specification list each and every promoter that might be used with the invention. Rather, one may rely on the many promoters known in the art to be useful in initiation transcription of a proximal gene. Indeed, as set forth in the MPEP: a patent need not teach, and preferably omits, what is well known in the art. *In re Buchner*, 929 F.2d 660, 661, 18 USPQ2d 1331, 1332 (Fed. Cir. 1991); *Hybritech, Inc. v. Monoclonal Antibodies , Inc .*, 802 F.2d 1367, 1384, 231 USPQ 81, 94 (Fed. Cir. 1986), cert. denied, 480 U.S. 947 (1987); and *Lindemann Maschinenfabrik GMBH v. American Hoist & Derrick Co.*, 730 F.2d 1452, 1463, 221 USPQ 481, 489 (Fed. Cir. 1984).

Applicants respectfully submit that current Claim 1 recites a replication-competent adenovirus vector comprising an adenovirus gene essential for replication under transcriptional control of an Epstein Barr Virus (EBV)-specific transcriptional regulatory element (TRE) comprising a sequence selected from the group consisting of a sequence upstream of the translational start codon for the LMP1 gene, presented as SEQ ID NO:1, a sequence upstream of the translational start codon for the LMP2A gene, presented as SEQ ID NO:2 and the Cp promoter sequence presented as SEQ ID NO:3. The EBV-TRE elements recited in the claims are described in the specification as EBV specific transcriptional response elements at least in: paragraph [0021] which describes LMP1 (SEQ ID NO:1) that contains two distinct promoters, termed "ED-L1"; and "L1-TR; paragraph [0027] which describes LMP2A (SEQ ID NO:2); paragraph [0028] which describes the Cp promoter (SEQ ID NO:3); and paragraph [0029] which describes the oriP FR enhancer for the LMP promoter.

One of ordinary skill in the art would be informed by the teachings of the subject specification, that applicants were in possession of the claimed invention when the application was filed.

In view of the above amendments and remarks, withdrawal of the rejection under 35 U.S.C. 112, first paragraph is respectfully requested.

Rejections under 35 U.S.C. § 112, second paragraph,

Claims 2-7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention for the reasons set forth on page 5 of the Office Action.

Claims 2 and 6 have been amended to clarify that the claimed EBV-specific TRE comprises a sequence is 5' to the translational start codon of the recited gene.

Applicants respectfully submit that the grounds for this rejection have been obviated by the amendments set forth above. Withdrawal of the rejection under 35 U.S.C. § 112, second paragraph, is respectfully requested.

Objections under 37 CFR 1.75(c)

Claims 12-13 stand objected to under 37 CFR 1.75(c) as being of improper dependent form for failing to further limit the subject matter of a previous claim.

Claim 1 has been amended to recite a replication-competent adenovirus vector comprising a first adenovirus gene essential for replication under transcriptional control of an EBV-specific TRE. Claims 12 and 13 are directed to an adenovirus vector according to Claim 1, further comprising a second adenoviral genes co-transcribed under transcriptional control of said EBV-specific TRE. Hence current Claims 12 and 13 are of proper dependent form.

CONCLUSION

In light of the above, Applicants submit that this application is now in condition for allowance and therefore request favorable consideration. If any issues remain which the Examiner feels may be best resolved through a personal or telephonic interview, the Examiner is respectfully requested to contact Applicants' counsel, Linda R. Judge at (415) 836-2586.

Respectfully submitted,

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